

### REMARKS

After entry of the Amendment, claims 1-21 are pending in the application. Claims 1-21 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Omata. In addition, claims 1-21 have been rejected under 35 U.S.C. §112 as being indefinite, and the Examiner has objected to the claims, drawings and specification for various informal reasons.

With this Amendment, Applicants have amended claims 1-21. Such amendments are fully supported by the specification, claims and drawings as originally filed. No new matter has been entered. In light of the foregoing amendments and the following remarks, Applicants respectfully submit that the application is in suitable condition for allowance; notice of which is requested. Reconsideration of the application as amended is requested.

#### **Drawings:**

Figure 1 has been corrected to show head portion 9. Figure 5 has been amended to include the label "Tissue Specimen Number" on the X-axis. Fig. 29a has been deleted from the specification in paragraph [0065], the only place that reference number is used, and has been replaced with "not shown." Applicants have submitted replacement pages 1/5 and 5/5 and respectfully request that the Examiner enter them.

#### **Abstract:**

The abstract has been amended to be between 50 and 150 words. The term "said" has also been removed.

#### **Specification:**

Paragraphs [0005], [0050], [0054], [0058], [0060], [0065], [0066] and [0068] of the specification have been amended to comply with the Examiner's request for correction. Paragraph [0050.1] has been added to include Fig. 2A in the BRIEF DESCRIPTION OF THE DRAWINGS. Section titles have also been added for clarity.

#### **Claim Objections:**

All of the Examiner's claim objections have been addressed.

**Rejections under 35 USC §112:**

The Examiner rejects claim 12 as being indefinite due to the unclear relationships between structures. Claim 12 has been amended to clarify the relationship between structures, support for which is found in paragraph [0026] of the specification.

The Examiner rejects claim 16 as being indefinite due to the term "it." The term has been replaced with "periodically displaceable body" to clarify the claim.

The Examiner rejects claims 1-21 in general as being narrative and indefinite. Care was taken to amend the claims to clarify the elements recited, remove indefinite terms, correct grammatical errors and correct antecedent basis.

Applicants respectfully submit that the claims as amended are no longer indefinite and request the rejection under §112 be removed.

**Rejections under 35 USC §103(a):**

Claims 1-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Omata. The Examiner contends that Omata teaches all of the elements of claim 1 except for the excitation frequency, maximum stroke length and displacement force. The Examiner states that it would have been an obvious matter of design choice to use the recited excitation frequency, maximum stroke length and displacement force, and Applicant has not disclosed that these measurements provide an advantage. Applicant respectfully disagrees.

Omata discloses an elasticity measuring device with a plurality of probes at the end of resilient arm members. (See [0010]-[0011] and Fig. 2) Movement of the probes into and out of the tissue is achieved by moving a sleeve over the resilient arm members. Movement of the sleeve can be performed manually or with a motor. ([0039]) The probes can be opened and closed in an umbrella fashion by movement of the sleeve. ([0040]) Hysteresis is the measurement of the contact pressure against the biological tissue. Specifically, the stress when the probes are driven to press onto and return from the biological tissue, the stress detected by the stress detection sensor. ([0025]) In another embodiment, balloons are secured to the probe base and are pumped up and deflated to move into and out of the tissue. ([0041] and Fig. 3) The

probes are gradually moved against the tissue and then removed therefrom. By correlating the stress  $F$  and the changes in the deviation magnitude  $X$ , the hysteresis of the elasticity of the tissue is determined. ([0045])

In contrast, Applicant discloses a device that measures a dynamic modulus achieved not through use of a single hysteresis loop as with Omata, but rather by using an oscillating device that is subject to periodic displacement. The periodic displacement subjects the tissue to a sinusoidal strain, as is explained in paragraphs [0008] and [0023] of Applicant's disclosure. The dynamic modulus is a complex number corresponding to  $(E_1 + iE_2)$  that represents visco-elastic properties relating the time-varying stress to strain history, as well as to the time-varying strain. ([0008]) To calculate this complex dynamic modulus, particular excitation frequency, maximum stroke length and displacement force are used depending on the tissue to be diagnosed. ([0021]) All materials show visco-elastic properties in some range of strain, but the identification of the sensitive range for biological materials required significant experimentation using a set of samples which contain a range of proportions of the histological components or other quality factors it is of interest to identify. ([0022]) During diagnosis, by repeating periodical displacement at a variety of different vibrational frequencies, the dynamic modulus of the tissue can be generated. ([0028])

Applicant submits that the excitation frequency, maximum stroke length and displacement force recited in claims 1, 18 and 21 are not obvious design choices, and Applicant has claimed these particular measurements because they were discovered during experimentation to provide the data necessary to calculate the dynamic modulus. Because Omata does not teach, disclose or render obvious all of the elements of claims 1, 18 and 21, Applicant respectfully submits that these claims are in condition for allowance.

Claims 2-17 depend from claim 1 and include all of the limitations therein. Because of this dependency, Applicant submits that claims 2-17 are also in condition for allowance.

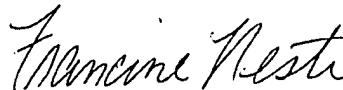
Claims 19 and 20 depend from claim 18 include all of the limitations therein. Because of this dependency, Applicant submits that claims 19 and 20 are also in condition for allowance.

Additionally, claim 21 recites in its preamble "a method of diagnosing a condition manifested by a histological abnormality." The method of claim 21 can differentiate between benign and malignant tissue to diagnose cancerous tissue. ([0060]) The results are be compared to known tissue profiles to complete the diagnosis, as recited in claim 21. Omata only discloses quantitative measurement of tissue elasticity. The only specific use discloses in Omata is the evaluation of tissue with known elasticity problems, such as a urethra, so locate the weakness. ([0004]) There is no comparison of the results to known tissue profiles, nor is there any diagnosis, as required by claim 21. Applicant respectfully submits that Omata fails to teach, suggest or render obvious many of the elements of claim 21. Therefore, claim 21 is in condition for allowance.

It is submitted that this Amendment has antecedent basis in the application as originally filed, including the specification, claims and drawings, and that this Amendment does not add any new subject matter to the application. Consideration of the application as amended is requested. It is submitted that this Amendment places the application in suitable condition for allowance; notice of which is requested.

If the Examiner feels that prosecution of the present application can be expedited by way of an Examiner's Amendment, the Examiner is invited to contact the Applicant's attorney at the telephone number listed below.

Respectfully submitted,



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October 8, 2008